

**REMARKS**

By this reply, Applicant amends claims 1, 6, 7, 17, 19-21, 27-30, 55, and 58; cancels claims 5, 10-13, 26, 37, 59, and 60; and adds new claim 61. Accordingly, claims 1, 6-9, 14-25, 27-36, 55-58, and 61 are pending in this application. Of those pending claims, claims 9, 17-25, and 27-36 were previously withdrawn. No new matter has been added by this reply.

In the Office Action, the Examiner took the following actions:

- (a) rejected claims 1, 5-8, 14, 55, 57, 58, and 60 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,488,877 to Klein et al. ("Klein");
- (b) rejected claims 1, 5-8, 14, and 55-60 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,810,721 to Mueller et al. ("Mueller");
- (c) rejected claims 15 and 16 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klein; and
- (d) rejected claims 15 and 16 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mueller.

**I. Rejection of claims 1, 5-8, 14, 55, 57, 58, and 60 under 35 U.S.C. § 102(b) based on Klein**

In light of the amendments to independent claims 1, 55, and 58, Applicant requests withdrawal of the rejection of claims 1, 6-8, 14, 55, 57, and 58 under 35 U.S.C. § 102(b), as anticipated by Klein.

**A. Amended independent claim 1**

Amended independent claim 1 now recites, *inter alia*,

the retractor includes a distal portion including a portion of the retracting sleeve and a distal ring; and an insertion tool . . . including a groove for receiving the distal portion such that, in a deployment position, the distal ring is positioned to intersect a central longitudinal axis of the insertion tool.

Support for amended independent claim 1 can be found at least in FIGS. 43-46 that correspond to the elected embodiment.

Klein fails to teach or suggest at least these features recited in amended independent claim 1. What Klein discloses is an implant device including a rigid tubular device 10 and attached flexible sleeve member 12, where rigid tubular device 10 include a ridge 46 that is held by a forceps during implantation and needle change operations. See Klein, column 2, lines 60-62; and column 4, lines 5-8. With respect to the forceps, Klein states that “[a] suitable forceps tool for gripping ridge 44 is described in co-pending application, Serial No. 209,058, filed 11/21/80, the disclosure of which is incorporated herein by reference.” Id. at column 4, lines 8-10. The co-pending application being referred to in Klein is U.S. Patent No. 4,776,843 to Martinez et al. (“Martinez”). In Martinez, a stem clamping forceps 100 includes arms 101 and 102 with grooves 105 and 106 for engaging a flange 42 of a stem 11. See Martinez, column 8, lines 50-61; and FIGS 14-18.

One of the deficiencies of Klein is that grooves 105 and 106 in forceps 100 of Martinez do not receive ridge 46 such that, in a deployment position, a cuff 18<sup>1</sup> is positioned to intersect a central longitudinal axis of forceps 100. See Klein, column 4, lines 5-8; and Martinez, column 8, lines 50-61. Rather, grooves 105 and 106 receive ridge 46 such that, in a deployment position, cuff 18 (located a distance away from ridge 46 and the central longitudinal axis of forceps 100) does not intersect the central longitudinal axis of forceps 110. See Id. at FIG. 2; and Martinez, FIG. 15. Thus, Klein

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<sup>1</sup> Page 2 of the Office Action asserts that cuff 18 of Klein corresponds to a distal ring.

fails to teach or even suggest, “an insertion tool . . . including a groove for receiving the distal portion such that, in a deployment position, the distal ring is positioned to intersect a central longitudinal axis of the insertion tool,” as recited by amended independent claim 1. For at least this reason, Klein and Martinez fail to anticipate amended independent claim 1. The timely allowance of amended independent claim 1 is therefore respectfully requested.

**B. Amended independent claim 55**

Amended independent claim 55 now recites, *inter alia*, “the insertion tool includes a unitary shaft including a distal end portion, the distal end portion including a retractor receiving portion . . . including an opening facing the wound opening during deployment.” Support for amended independent claim 55 can be found at least in FIGS. 43-46, which correspond to the elected embodiment.

Klein and Martinez fail to teach or suggest at least this feature recited in amended independent claim 55. While arms 101 and 102 of Martinez include grooves 105 and 106, respectively, for receiving a ridge on an implant device, neither of those grooves has an opening that faces a wound opening during deployment. See FIGS. 14-16 of Martinez. Since groove 105 of arm 101 does not include an opening facing a wound opening during deployment, and groove 106 of arm 102 is similarly deficient, Klein and Martinez fail to teach or even suggest, “the insertion tool includes a unitary shaft including a distal end portion, the distal end portion including a retractor receiving portion . . . the retractor receiving portion including an opening facing the wound opening during deployment,” as recited in amended independent claim 55.

Accordingly, the references fail to anticipate amended independent claim 55. The timely allowance of amended independent claim 55 is therefore respectfully requested.

**C. Amended independent claim 58**

Amended independent claim 58 now recites, *inter alia*, “an insertion tool . . . wherein the insertion tool includes a groove for receiving the distal portion such that, in a deployment position, the distal ring extends generally in the direction of the longitudinal axis, and a taper in a plane normal to a plane formed by the distal ring in the deployment position.” Support for amended independent claim 58 can be found at least in FIGS. 43-46, which correspond to the elected embodiment. Klein and Martinez fail to teach or even suggest at least this feature of amended independent claim 58. Forceps 100 of Martinez do not include a taper in a plane formed by cuff 18<sup>2</sup> in the deployment position. See FIG. 1 of Klein, as well as column 4, lines 5-8; and FIGS. 14-16 of Martinez, as well as column 8, lines 50-61. Accordingly, the references fail to anticipate amended independent claim 58. The timely allowance of amended independent claim 58 is therefore respectfully requested.

**D. Dependent claims 6-8, 14, and 57**

Claims 6-8, 14, and 57 depend from one of amended independent claims 1, 55, and 58, and are allowable for at least the reasons stated above that amended independent claims 1, 55, and 58 are allowable. In addition, each of the dependent claims recites unique combinations that are neither taught nor suggested by the cited art, and therefore each is also separately patentable.

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<sup>2</sup> Page 2 of the Office Action asserts that cuff 18 of Klein corresponds to a distal ring.

**II. Rejection of claims 1, 5-8, 14, and 55-60 under 35 U.S.C. § 102(b) based on Mueller**

In light of the amendments to independent claims 1, 55, and 58, Applicant requests withdrawal of the rejection of claims 1, 7, 8, 14, and 55-58 under 35 U.S.C. § 102(b), as anticipated by Mueller.

**A. Amended independent claim 1**

Mueller discloses “a particularly advantageous retractor system 80 comprises retractor 81 and a delivery device including an obturator 88 having a longitudinal channel 89 with inward facing surfaces 90 which restrain the anchor ring therebetween.” Mueller, column 10, lines 46-50. Mueller also discloses that “retractor 81 comprises an anchoring ring 82, tabs 84, and an outer ring 86. Tabs 84 have a tissue restraining portion 98 from which tethers 96 extend.” Id. at column 10, lines 35-37.

But Mueller does not teach or suggest a groove for receiving a distal portion of retractor 81. Rather, in Mueller, longitudinal channel 89 receives the distal portion of retractor 81. See FIG. 10B in Mueller. Thus, Mueller fails to teach or even suggest “the insertion tool including a groove for receiving the distal portion such that, in a deployment position, the distal ring is positioned to intersect a central longitudinal axis of the insertion tool.” For at least this reason, Mueller fails to anticipate amended independent claim 1.

Even if longitudinal channel 89 could somehow be interpreted as being a groove, Mueller would still be deficient. This is because the distal portion of retractor 81 that is received in longitudinal channel 89 includes tethers 96, not a retracting sleeve. Thus, Mueller also fails to teach or suggest, “the retractor includes a distal portion including a portion of the retracting sleeve and a distal ring; and an insertion tool . . . including a

groove for receiving the distal portion,” as recited in amended independent claim 1. For at least this additional reason, Mueller fails to anticipate amended independent claim 1. The timely allowance of amended independent claim 1 is therefore respectfully requested.

**B. Amended independent claim 55**

Obturator 88 of Mueller includes plate-like structures, one on each side of longitudinal channel 89. See FIG. 10B of Mueller, as well as column 10, lines 46-50. But neither of the plate-like structures includes an opening facing a wound opening during deployment of retractor 81. Thus, Mueller fails to teach or even suggest “the insertion tool includes a unitary shaft including a distal end portion, the distal end portion including a retractor receiving portion . . . the retractor receiving portion including an opening facing the wound opening during deployment,” as recited in amended independent claim 55. Accordingly, Mueller fails to anticipate amended independent claim 55. The timely allowance of amended independent claim 55 is therefore respectfully requested.

**C. Amended independent claim 58**

As explained in column 10, lines 46-50 of Mueller, obturator 88 includes a longitudinal channel 89. Longitudinal channel 89 that receives the distal portion of retractor 81, not a groove. Thus, Mueller fails to teach or suggest, “an insertion tool . . . wherein the insertion tool includes a groove for receiving the distal portion,” as recited in amended independent claim 58.

Even if longitudinal channel 89 could somehow be interpreted as being a groove, Mueller would still be deficient. This is because obturator 88 does not include a taper in

a plane normal to a plane formed by anchor ring 82 of Mueller in the deployment position of FIG. 10B. Rather, obturator 88 includes a taper (see the beveled portions at the lower end of obturator 88 in FIG. 10B) in a plane parallel to a plane formed by anchor ring 82 in the deployment position of FIG. 10B. Thus, Mueller would still fail to teach or suggest, “the insertion tool includes a groove for receiving the distal portion such that, in a deployment position, the distal ring extends generally in the direction of the longitudinal axis, and a taper in a plane normal to a plane formed by the distal ring in the deployment position,” as recited by amended independent claim 58.

**D. Dependent claims 7, 8, 14, 56, and 57**

Claims 7, 8, 14, 56, and 57 depend from one of amended independent claims 1, 55, and 58, and are allowable for at least the reasons stated above that amended independent claims 1, 55, and 58 are allowable. In addition, each of the dependent claims recites unique combinations that are neither taught nor suggested by the cited art, and therefore each is also separately patentable.

**III. Rejection of claims 15 and 16 under 35 U.S.C. § 103(a) based on Klein**

In light of the amendment to independent claim 1, Applicant requests withdrawal of the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) over Klein. As discussed above, Klein fails to teach or suggest each of the limitations in amended independent claim 1, from which claims 15 and 16 depend. Even if stem clamping forceps 100 of Klein could be modified with respect to its dimensions in the manner suggested on page 3 of the Office Action, such a modification would not remedy the deficiencies of Klein set forth in the discussion of amended independent claim 1. Therefore, claims 15

and 16 are allowable at least for the same reasons that amended independent claim 1 is allowable.

**IV. Rejection of claims 15 and 16 under 35 U.S.C. § 103(a) based on Mueller**

In light of the amendment to independent claim 1, Applicant requests withdrawal of the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) over Mueller. As discussed above, Mueller fails to teach or suggest each of the limitations in amended independent claim 1, from which claims 15 and 16 depend. Even if stem clamping forceps 100 of Mueller could be modified with respect to its dimensions in the manner suggested on page 3 of the Office Action, such a modification would not remedy the deficiencies of Mueller set forth in the discussion of amended independent claim 1. Therefore, claims 15 and 16 are allowable at least for the same reasons that amended independent claim 1 is allowable.

**V. Request for Rejoinder**

Applicant requests that previously withdrawn claims 9, 17-25, and 27-36 be rejoined with the elected claims in this application. Claims 9, 17-25, and 27-36 all depend either directly or indirectly from amended independent claim 1, and thus, are allowable for at least the same reasons that amended independent claim 1 is allowable. In addition, each of these withdrawn dependent claims recites unique combinations that are neither taught nor suggested by the cited art, and therefore each is also separately patentable.

**Conclusion**

In view of the foregoing amendments and remarks, Applicant submits that this claimed invention is neither anticipated nor rendered obvious in view of the prior art




references cited against this application. Applicant therefore requests the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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